

Application No. 09/915,580

REMARKSStatus of the Claims

Claims 1-11 are pending in this application. No claims have been canceled, added or amended. Applicants submit the following arguments in support of the allowability of the claims. Applicants respectfully request that the Examiner enter this Reply as no new issues have been raised.

Priority

Contrary to the Examiner's statements in the Office Action, an Applicant need only provide a certified copy of the originally filed foreign application. Such a copy has been filed. No translation is required according to 37 CFR 1.55 and MPEP 201.13. As such, Applicants respectfully request that this objection be withdrawn as improper.

Information Disclosure Statement

Applicants submit that all references cited in the specification were submitted in an Information Disclosure Statement dated July 27, 2001. As such, Applicants respectfully request that this objection be withdrawn as improper.

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Rejections under 35 USC 103(a)

The Examiner maintains the rejection of claim 1 as obvious over Yamao USP 6,030,845 in view of the abstract of JP 60047962. Applicants traverse the rejection and respectfully request the withdrawal thereof.

In response to Applicants' arguments in the Reply filed May 27, 2003, the Examiner states that hemolysis may occur before or after the agglutination reaction. The Examiner points to column 2, line 4 of Yamao '845. The Examiner states that the order of lysis is not critical to the invention and that Yamao '845 and JP '962 teach simultaneous lysis and agglutination.

Applicants submit that the present invention is directed to a whole blood immunoassay comprising the steps of (i) mixing a whole blood sample with sensitized insoluble carrier particles to cause an immune agglutination; (ii) diluting the resulting agglutination mixture with an aqueous solution containing an erythrocyte lysing agent to lyse erythrocytes; and (iii) determining the degree of agglutination of the resulting whole blood sample.

Neither Yamao '845 nor JP '962 discloses an immunoassay for whole blood where the whole blood is first subjected to the agglutination reaction and then lysed subsequent to the agglutination reaction. Yamao '845 discloses an immunoassay where the agglutination reaction occurs simultaneously with hemolysis of the whole blood cells as opposed to the reaction occurring before

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hemolysis as in the present invention. In fact, Yamao '845 teaches away from first subjecting the whole blood to the agglutination reaction and then lysing subsequent to the agglutination reaction. Yamao '845 teaches that lysis should not be carried out in a manner that would affect agglutination. See column 6, lines 5-8 which disclose that the surface-active agents inhibit the agglutination reaction. Therefore, one of ordinary skill in the art would not be motivated to alter the Yamao '845 assay to first subject the whole blood to the agglutination reaction and then lysis. In addition, in Example 4 of Yamao '845, the agglutination reaction was carried out after lysis, as would be expected from the complete disclosure in the specification in Yamao '845.

JP '962 discloses a whole blood immunoassay where the lysing agent is added to the whole blood and lysis occurs prior to agglutination. In the Office Action, the Examiner stated that hemolyzing agents cause hemolysis of erythrocytes, which interfere with the agglutination reaction by referring to the abstract of JP '962. Applicants respectfully disagree with the Examiner and provide an English translation of the complete specification of JP '962. (A copy is attached hereto.) Upon review of the English translation, Applicants submit that the Examiner's statement is not supported by the entire specification of JP '962. As such, Applicants respectfully submit that the Examiner's statement is not correct and that JP '962 fails to suggest that lysis should occur

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after agglutination. As such, the Examiner's reliance on JP '962 is insufficient in combination with Yamao '845 to disclose or suggest all the elements of the present invention.

The Examiner also maintains the rejection of claims 2 and 3 as obvious over Yamao '845 in view of the abstract of JP '962 and further in view of Bester et al. Applicants traverse the rejection and respectfully request the withdrawal thereof.

The Examiner cites Bester for disclosing optimization of the lysing agent, such as SDS. Bester also fails to disclose having agglutination occur prior to lysis. Inasmuch as Bester fails to compensate for the deficiencies in Yamao '845 and JP '962, as pointed out above, Applicants submit that this rejection should also be withdrawn for the reasons stated above.

Claims 4 through 9 are also rejected over Yamao '845 in view of the abstract of JP '962, Kosako USP 5,527,714 and Cohen USP 4,851,329. Applicants traverse the rejection and respectfully request the withdrawal thereof.

The Examiner cites Kosako '714 and Cohen '329 for teaching the step of determining the concentration of particles to have an assay with high sensitivity and specificity. Inasmuch as Kosako '714 and Cohen '329 fail to compensate for the deficiencies in Yamao '845 and JP '962, as pointed out above, Applicants submit that this rejection should also be withdrawn for the reasons stated above.

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The rejection of claim 10 is also maintained as obvious over Yamao '845 in view of the abstract of JP '962 and further in view of Holmes USP 4,830,969.

The Examiner relies on Holmes '969 for disclosing the reaction time and temperature. Holmes '969, however, fails to disclose a whole blood immunoassay where agglutination takes place prior to hemolysis. As such, Applicants submit that Holmes '969 also fails to compensate for the deficiencies in the primary and secondary references, Yamao '845 and JP '962, as pointed out above. Therefore, this rejection should be withdrawn.

Conclusion

As Applicants have addressed and overcome all objections and rejections in the Office Action, Applicants respectfully request that the objections and rejections be withdrawn and that the claims be allowed.


Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Kecia Reynolds (Reg. No. 47,021) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

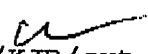
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If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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Attachment(s)